江西科伦医疗器械制造有限公司
JIANGXI KELUN MEDICAL DEVICES MANUFACTURING CO., LTD.

MAR 2 7 2014

Section 5 510(k) Summary K133493

(As required by 21 CFR 807.92(a))

5.1 Submitter Information

· Company: Jiangxi Kelun Medical Devices Manufacturing Co.,Ltd.

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336000 Yichun City, Jiangxi Province, P.R China

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· Email: kl-lanhai@kelun.com

· Contact: Lan Hai, General Manager

· Date: June 21, 2013.

5.2 Device Information

· Trade/Proprietary Name: Single Use Sterile Syringe with Needle;

· Model: 1ml, 2ml, 2.5ml, 5ml, 10ml, 20ml, 30ml, 50ml

· Common Name: Piston Syringe

· Classification: Device Class: 2
Review Panel: General Hospital
Name: Syringe, Piston/ Needle, Hypodermic, Single Lumen
Regulation Number: 21 CFR 880.5860 / 21 CFR 880.5570
Product Code: FMF/FMI

· Predicate Device: K111841 - Shifeng Disposable Syringe with or without needle manufactured by Chengdu Xinjin Shifeng Medical Apparatus & Instrument Co., Ltd.

· Device Description:

The Single Use Sterile Syringe with Needle belongs to standard piston. And there are eight models - 1ml,2ml,2.5ml,5ml,10ml,20ml,30ml and 50ml within the device, which enjoy the same stucture, that is, all of the eight models consists of a piston syringe comprised of a movable plunger, piston and a calibrated hollow barrel, at one end of which there is a male connector (nozzle) for fitting the female connector (hub) of a hypodermic single lumen needle, and a matching hypodermic single lumen needle which consists of a metal tube that is sharpened at one end and at the other end joined to a

female connector (hub) designated to mate with a male connector (nozzle) of a piston syringe.

· Intended Use:

Single Use Sterile Syringe with Needle is intended to inject fluids into or withdraw fluid from part of the body below the surface of the skin.

5.3 Comparison of Required Technology Characteristics

Item	Subject Device	Predicate Device
Syringe Type	Standard Syringe	Same
Intended Use(s)	Are intended to be used to inject fluid into or withdraw fluids from the body.	Same
Principle of Operation	The operation principle is pushing or pulling the plunger too inject fluid into or withdraw fluids from the body, suitable for human skin, muscle, intravenous injection, etc.	Same
Specific Drug Use	No	Same
Dimensions	Same length complying with ISO 7886-1, Clause 11.1	Similar
	Similar diameter	
	Similar tip type	
	Similar volumes	
Nozzle Type	Slip Tip	Same
Barrel Marking Specs	Complying with ISO 7886-1	Same
Gradations Legibility	Legible	Same
Lubricant Composition	Polydimethylsiloxane	Same
Lubricant Amount/cm^2	Accord with ISO 7886-1, Clause 8	Same
Barrel Transparency	Transparent	Same
Delivery Accuracy	Comply with ISO 7886-1,	Same

	Clause 10.1~10.4	
Reuse Durability	Not applicable, single use device	Same
Biocompatibility	Comply with ISO 10993	Same
Materials		
· Barrel	Polypropylene	Same
· Plunger	Polypropylene	Same
· Piston	Natural rubber	Similar
Labeling	Comply with ISO 7886-1, Clause 16	Same
Sterilization	ETO in fixed chamber	Same
Packaging	Comply with ISO 7886-1, Clause 15	Same
Needle & Needle Cover	Accord with the requirement of ISO 7864.	Similar

Brief Summary:

First, the Single Use Sterile Syringe with Needle incorporates the same syringe type, intended use and principle of mode with the predicate device. Secondly, the subject device shares almost the same design and fundamental technological characteristics with the predicate device, for example, they both have no specific drug use, enjoy almost the same physical, mechanical and biological specifications, share the same sterilization methods and qualified labeling and packaging. Though they are not identical in dimensions, piston material and needle specifications, such difference have been further verified by relevant FDA recognized standards, thus will not bringing new safety and effectivity concerns.

5.4 Discussion of Tests Performed

· Clinical Tests:

Clinical testing is not required for a typical piston syringe device.

· Non-Clinical Tests

The subject device was tested to evaluate its safety and effectiveness according to the following standards:

a. Biocompatibility Test according to ISO 10993-4: Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood, ISO 10993-5: 2009, Biological evaluation of medical devices-Part 5: Tests for In Vitro cytotoxicity, ISO 10993-10: 2010, Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization and ISO 10993-11:2006/(R)2010, Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity according to the recommendations in the Blue Book Memorandum #G95-1, entitled Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing".

b. Syringe Performance Effectiveness Test according to ISO 7886-1:1993, Sterile hypodermic syringes for single use - Part 1: Syringes for manual use and ISO 594/1, Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements.

c. Needle Performance Effectiveness Test according to ISO 7864:1993, Sterile hypodermic needles for single use, ISO 594/1, Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements and ISO 9626 First edition 1991-09-01, AMENDMENT 1 2001-06-01 Stainless steel needle tubing for the manufacture of medical devices.

· Steriilzation

Moreover, the sterilization conditions are validated in accordance with the company's own "Ethylene Oxide Steriliztion Verification Scheme" which is compiled on the basis of the requirements of ISO11135-1: 2007 from January 24,2013 to March 2,2013 to provide a Sterility Assurance

Level(SAL) of 10^{-6}.

And Ethylene Oxide residual levels after 7 days aeration from EtO sterilization will not exceed the maximum daily dose levels proposed in ISO 10993-7:2008.

5.5 Conclusion:

First, the subject device Single Use Sterile Syringe with Needle enjoys the same intended use and similar technological characteristics with the predicate device. Besides, the performance safety and effectiveness of the subject device has been verified in accordance with the above FDA recognized standards, thus being considered to be as safe and effective as the predicate device.

In a word, it is reasonable for us to conclude that the subject device is substantially equivalent to the predicate device according to the above analysis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 27, 2014

Jiangxi Kelun Medical Devices Manufacturing Company, Ltd
C/O Helen Nan
General Manager
Room 302, NO. 21 Building, Kaiyu Garden, Xishan South Road
Wenzhou, Zhejiang 325000

Re: K133493
Trade/Device Name: Single Use Sterile Syringe with Needle
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF/FMI
Dated: June 21, 2013
Received: March 7, 2014

Dear Ms. Nan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K133493

Device Name
Single Use Sterile Syringe with Needle

Indications for Use *(Describe)*

Single Use Sterile Syringe with Needle is intended to inject fluids into or withdraw fluid from, parts of the body below the surface of the skin.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Digitally signed by
Richard C. Chapman
Date: 2014.03.27
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